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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HORNING, MICHELLE S	
ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/599,098	SUTTON ET AL.	
	Examiner	Art Unit	
	MICHELLE S. HORNING	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *84-103* is/are pending in the application.

5a) Of the above claim(s) *91-96* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *84-90 and 97-103* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *9/16/2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/22/2007+10/13/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 84-90 and 97-103 are under current examination.

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 9/26/2011 is acknowledged. The traversal is on the ground(s) that the combined teachings of WO 2004/003226, WO 2000/46357 and WO 2002/053723 does not suggest method and products of the claimed invention and therefore, does not destroy unity of invention.

This is not found persuasive because as discussed below, the prior art teaches the claimed invention; note that US Patent 6913896 is cited instead of the WO 2000/46357 document. Applicant acknowledges that the '357 reference discloses an assay based on a thermostable kinase but alleges it not used to validate effects of a treatment process on an infectious agent. As discussed below, the reference provides a "screening of cleaning protocols to determine their suitability for the removal of TSE agents from surfaces..." using a thermostable kinase and this supports a validation of some TSE treatment method; see col. 3, lines 1+ of this reference. Applicant also argues that reference '723 discloses the use of a thermostable proteolytic enzyme to inactivate TSE infectious but the kinase does not validate the effects on the infectious agent. In response, the teachings of the '357 reference is cited for teaching such validation whereas the '723 reference is cited for teaching a TSE treatment method. See instant claim 84 which provides that such treatment method comprises exposure to an enzyme and this comprises a thermostable proteolytic enzyme.

The requirement is still deemed proper and is therefore made FINAL.

Claims 91-96 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention(s), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/26/2011.

The elected species are:

A. proteins;

B. adenylate kinase;

C. SEQ ID NO: 2; and,

D. SEQ ID NO: 27 (search was extended to SEQ ID NO: 26, taught by Kath *et al.*).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 84-90 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a step(s) which would result in the validation of a treatment process for reducing the amount of activity of a contaminating biological agent in a sample as required in the preamble. As written, it is not clear how the single step of exposing an indicator and agent to a treatment process correlates to the required validation as claimed in the preamble. Additional step(s) leading to the achievement of the claimed validation or a correlation between the step and the claimed validation would rectify this rejection; for example, measuring the

resulting kinase activity wherein a reduction indicates a reduction in amount or activity *etc*....

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 84-90 and 97-103 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of US Patent 6913896 (see attached form 892), WO 02/053723 (cited by the IDS, hereinafter as "Raven") and Kath *et al.* (*Archives of Biochemistry and Biophysics*, 1993-see attached form 892).

US Patent 6913896 teaches a method for validating a treatment process for reducing the amount or activity of a contaminating biological agent, such as a

transmissible spongiform encephalopathy, in a sample; see col. 3, lines 1+ for "screening of cleaning protocols to determine their suitability for the removal of TSE agents from surfaces..." wherein TSE is a transmissible spongiform encephalopathy. This reference describes using a solid support, including a dip-stick or a bead wherein a thermostable adenylate kinase is immobilized; see col. 5, lines 9+ and lines 31+, instant claims 85-88, 98, 99 and 103 and elected species B noted above. The authors also describe measuring reporter adenylate kinase activity via ATP bioluminescence wherein the amount of the reporter adenylate kinase is substantially in proportion to the amount of analyte (or TSE agent) present; see col. 1, lines 14+, col. 3, lines 24+, Example 1 and instant claims 97 and 102 for “measuring a residual kinase activity”. Note that because the amount of reporter adenylate kinase is proportional to the contaminating biological agent (or TSE agent), this teaching provides a method of correlating the amount of a contaminating biological agent in a sample with the thermostable kinase activity as well as measuring the amount or activity of the contaminating biological agent of instant claim 102, lines 1-3 and step (iv). Also, measuring a “residual” kinase activity is described by this reference because the authors describe eliminating any endogenous adenylate kinase that is present in a sample so that only the remaining thermostable reporter kinase activity is measured; see col. 3, lines 29+. It is noted here that this reference provides that an adenylate kinase may be produced via the *Sulfophoboccoccus* genera as well as the use of *E. coli* to produce homogenous adenylate kinase; see col. 6, lines 3+ and col. 8, line 20.

While this patent describes validating a treatment process in inactivating a protein, a solid support, *etc.*, the reference does not explicitly describe treatment processes which include an exposure of enzyme, pH or temperature (see claims 84, 97 and 102). Also, this patent does not explicitly describe the protein set forth by SEQ ID NO: 2 or the nucleotide sequence set forth by SEQ ID NO: 26; see elected species C and D noted above and instant claims 89, 90, 100 and 101. This patent does not teach "comparing said residual activity to a predetermined kinase activity, or comparing said reduction in kinase activity to a predetermined reduction in kinase activity, wherein the predetermined kinase activity or predetermined reduction in a kinase activity corresponds to a confirmed reduction in the amount or activity of the contaminating biological agent under identical treatment process conditions"; see instant claim 98. This patent does not teach the method step of "(v) repeating steps (i) to (iv), wherein at least one parameter of the treatment process is changed"; see instant claim 102.

Raven describes a method of inactivating a TSE agent (or reducing the activity of a contaminating biological agent in a sample; see instant claim 84) comprising exposing a TSE agent to a treatment process comprising a thermostable proteolytic enzyme at an elevated temperature; see abstract, p. 15+ disclosing homogenates as samples, and instant claims 84 (for treatment process including exposure to an enzyme) and 88 (for a TSE). Note that this reference discloses that a TSE biological agent comprises a prion protein; see abstract, p. 1, para, 2, instant claim 84 (for a protein as a contaminating biological agent) and elected species A noted above. It is noted here that Raven

describes multiple parameters that may be used in TSE inactivation, including acidic or alkaline pH; see abstract, p. 5, para. 2 and instant claims 84, 97 and 102.

Kath describes the identification, cloning and expression of the adenylate kinase gene from the thermoacidophilic bacterium *Sulfolobus acidocaldarius*; see title, abstract, Figure 2 on p. 407 and elected species B noted above. The protein provided by this paper meets the protein set forth by SEQ ID NO: 2 of instant claims 89 and 100. The authors note that this kinase is extremely thermophilic and that expression of this kinase has been achieved in *E. coli* with excellent yield; see introduction, col. 2. Also note is that this reference teaches the nucleotide sequence set forth by SEQ ID NO: 26 of instant claims 90 and 101; see Figure 2 and footnote 1 on p. 405 which provides Accession No. X73564.

It would have been obvious to one of ordinary skill in the art to combine the methods of US Patent 6913896 and Raven in order to validate a treatment process for reducing the amount or activity of a TSE agent using a thermostable kinase as an indicator. One would have been motivated to expose a combination comprising a thermostable kinase indicator and the contaminating biological agent to a treatment process comprising a thermostable protease enzyme and elevated temperatures for TSE inactivation or reduction because both the protease enzyme and the kinase indicator are thermally stable; thus, the enzyme and the indicator can withstand elevated temperatures.

It would have been obvious to one of ordinary skill in the art to use a known thermostable adenylate kinase, including that derived from *Sulfolobus acidocaldarius*, in

the method taught by the combination of US Patent 6913896 and Raven. One would have been motivated to do so because such kinase has been identified, successfully cloned and expressed as taught by Kath *et al.* Also, Kath *et al.* teachings that such kinase successfully grows in *E. coli* with excellent yield.

In view of "comparing said residual activity to a predetermined kinase activity, or comparing said reduction in kinase activity to a predetermined reduction in kinase activity, wherein the predetermined kinase activity or predetermined reduction in a kinase activity corresponds to a confirmed reduction in the amount or activity of the contaminating biological agent under identical treatment process conditions" of instant claim 98, such step would have been obvious to one of ordinary skill in the art at the time of the invention. One would have been motivated to do so in order to compare a kinase activity or reduction thereof to that of a *control* experiment wherein the activity or reduction thereof has been predetermined and confirmed for the advantages of quantifying the effectiveness of a given treatment process and adjusting various parameters as necessary in modulating the amount or activity of a contaminating biological agent being reduced.

In view of the method step of "(v) repeating steps (i) to (iv), wherein at least one parameter of the treatment process is changed" of instant claim 102, such a step would have been obvious to one of ordinary skill in the art at the time of the invention. One would have been motivated to change at least one parameter of the treatment process, such as changes in temperature or pH, for the advantage of optimizing results with the

result effective parameter of reducing the amount or activity of a TSE agent at a controlled rate.

There would have been a reasonable expectation of success given the underlying materials and methods are widely known and commonly used as demonstrated by the applied prior art (*e.g.* characterization of adenylate kinase from *Sulfolobus acidocaldarius*, treatment processes for a TSE agent, *etc.*).

The invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 84-90 and 97-103 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12, 16-21 and 23-35 of copending Application No. 12/918628 (PG PUB 20110177539). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to the same method comprising the same steps, including subjecting a sample to a treatment process and use of an indicator such as kinase activity. Thus, the claims of the ‘628 application fall within the scope of the instant claims. It is noted here that the instant application is not related to the ‘628 application in view of either a divisional or a restriction.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE S. HORNING whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ZACHARIAH LUCAS can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MICHELLE S HORNING/
Examiner, Art Unit 1648